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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/858,349      | 05/15/2001  | Daniel Plaksin       | 87534-2800          | 2778             |

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| EXAMINER |
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FRIEND, TOMAS H F

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1639

DATE MAILED: 05/01/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/858,349

Applicant(s)

PLAKSIN, DANIEL

Examiner

Tomas Friend

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **Detailed Action**

### **Status of the Application**

A raw sequence listing was received on 08 August 2001 (Paper No. 5).

### **Status of the Claims**

Claims 1-33 are pending in the present application and are subject to restriction and election of species requirements.

### **Restriction**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-12 and 19, drawn to a polypeptide comprising a single domain of the variable region of the heavy chain of an antibody, classified in class 530, subclass 350.
  - II. Claims 13-18 and 20, drawn to a peptide capable of binding a specific antigen of interest, classified in class 530, subclass 300.
  - III. Claims 21-23, drawn to a phage-display library, classified in class 435, digest 24.
  - IV. Claims 24-27, drawn to an isolated phage clone, classified in class 435, subclass 320.1.
  - V. Claims 28 and 32, drawn to a method of treatment of a disease comprising the administration of a polypeptide according to claim 1 or 9, classified in class 424, subclass 130.01.
  - VI. Claims 29 and 33, drawn to a method of diagnosing a disease comprising the administration of a polypeptide according to claim 1 or 9, classified in class 424, subclass 130.01.

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- VII. Claim 30, drawn to a method of treatment of a disease comprising the administration of a polypeptide according to claim 13, classified in class 424, subclass 133.1.
- VIII. Claim 31, drawn to a method of diagnosing a disease comprising the administration of a polypeptide according to claim 13, classified in class 424, subclass 133.1.

The inventions are distinct, each from the other because:

- 2. Inventions I and II and Inventions V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case either of the compositions of Inventions I or II may be used to treat or diagnose a disease.
- 3. Inventions V-VIII are different and patentably distinct methods because they involve different method steps, starting materials, reagents, and/or reaction conditions and/or produce different products or results. For example methods of diagnosis and treatment result in different outcomes. The methods of Inventions V and VI require different compositions from the methods of Inventions of VII and VIII.
- 4. Inventions I-IV are different and patentably distinct compositions because they have different chemical and/or physical structures with different chemical, physical, and/or biological properties and require different materials and methods for their use and making. For example, the compositions of Inventions I and II are a polypeptide and a peptide while Inventions III and IV are phage(s) that need not comprise the peptide or polypeptide of Inventions II or I. Invention III is a single phage while Invention IV is a plurality of phages. Invention I is a polypeptide comprising a single-domain of the variable region of the heavy chain of an antibody,

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while Invention II is a peptide derived from the randomized sequence of the CDR3 region of a polypeptide.

5. Inventions III and IV are unrelated and patentably distinct to Inventions V-VIII because the compositions of Inventions II and IV are not disclosed as being used in or produced by the methods of Inventions V-VIII.

6. Because these inventions are distinct for the reasons given above and

- a. have acquired a separate status in the art as shown by their different classification ;
- b. have different and separately burdensome: manual and/or computer: structure, name and bibliographical searches; and
- c. have divergent subject matter, restriction for examination purposes as indicated is proper.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under CFR 1.17(h).

#### **Election of Species**

8. This application contains claims directed to patentably distinct species of the claimed invention. In addition to electing one of Inventions I - VIII, applicant is required to elect:

- A. an ultimate species (i.e. amino acid sequence) of peptide or polypeptide AND
- B. species of antigen of interest (Inventions I, II, and IV-VIII) or species of VH/VL interface (Invention III).

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The species are distinct, each from the other, because they have different structures with different chemical, physical, and/or pharmacological properties. Therefore, different issues of enablement and patentability apply to each species and each species represents patentably distinct subject matter.

9. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

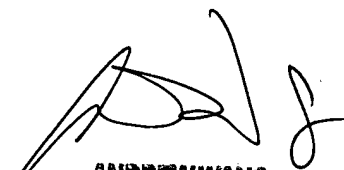
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Tomas Friend**, telephone number (703) 308-4548. The examiner's schedule is normally four, ten-hour days per week that includes Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Tomas Friend, Ph.D.

26 April 2003

  
**ANDREW WANG**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**